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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,546	09/29/2003	Masato Some	Q77645	7516
23373	7590	12/15/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			WHALEY, PABLO S	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/671,546	SOME ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

CLAIMS UNDER EXAMINATION

Claims herein under examination are Claims 1-8. Claims 5-8 are newly added. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

PRIORITY

Applicant's arguments directed to foreign priority are convincing. Requirement for including a first sentence containing the priority information is withdrawn. Acknowledgement of foreign priority to JAPAN 285102/2002, filed 9/30/2002, is granted.

DRAWINGS

The replacement drawings filed 09/20/2006 are acceptable.

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Applicant's arguments, filed 09/20/2006, that claims 1-4 recite a concrete, tangible, and useful result is not deemed to be persuasive. The Examiner appreciates the applicant's response, however this rejection is maintained over claims 1-4, for the reasons set forth below, and newly applied to claims 5-8 as necessitated by amendment.

Claims 1-8 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. A statutory process must include a step of a physical transformation of matter, or produce a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))].

Claims 1-8 are directed to methods for normalizing gene expression data comprising steps that do not include a physical transformation of matter. Claims 1, 3, 5, and 7 recites steps of "indicating" and "plotting", the specification has not provided limiting definitions such that these steps are necessarily physical steps or steps communicated to a user. Therefore, the instant claims encompass non-physical (i.e. *in-silico*) method steps which do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful result (i.e. a specific and substantial). In the instant case, claims 1, 3, 5, and 7 result in the step of dividing data "concerning expression quantities." As the claims do not recite any result that is actually

Art Unit: 1631

communicated to a user, the claims do not recite a tangible result such that it is useful to one skilled in the art. For these reasons, the instant claims are not statutory.

This rejection could be overcome by amending the claims to recite that a result of the method is "displayed" or "outputted" (e.g. output to a user, a display, a memory, or another computer, etc.), or by amending the claims to include a step of a physical transformation of matter (e.g. assay). For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3, line 10, recite the limitation "calculating a coefficient from a value of an intercept" (step ii). Applicant's argument's filed 09/20/2006 are directed to limitations that are not in the instant claims, therefore this rejection is maintained and reiterated. As written, it remains unclear in what way the said "coefficient" is related to the value of an intercept. Does the applicant intend for the coefficient to be "any" coefficient, or "a" specific coefficient. As applicant's argue that "10^a" is the coefficient corresponding to claim 1, the slope of "line 10" is the coefficient of claim 3, and "a" is the intended intercept, this should be clearly reflected in the

Art Unit: 1631

claim language to clarify this issue. Furthermore, the incorporation of specific equations the applicant points to in the specification could further serve to clarify this issue. Clarification is requested. The Examiner has interpreted these limitations broadly for purposes of applying prior art.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Applicant's have neglected to address this rejection in the response filed 09/20/2006, therefore this rejection is maintained and reiterated. The omitted steps are between steps (i) and (ii), as applicant discloses a step for calculating a coefficient from a "value of an intercept" that has not been previously determined. Clarification is requested.

Newly added claim 5, step ii, recites the limitation "calculating a coefficient from an intercept" (step ii). It is unclear in what way the said "coefficient" is related to said intercept. As this is a calculation, the incorporation of specific equations the applicant points to in the specification could further serve to clarify this issue. Clarification is requested. The Examiner has interpreted these limitations broadly for purposes of applying prior art.

Newly added claim 6 recites the same exact limitation as the claim from which is depends (claim 4). Therefore it is unclear in what way claim 6 further limits the method of parent claim 3. Clarification is requested.

CLAIM REJECTIONS - 35 USC § 102

Claims 3, 4, 6, 7, and 8 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Li et al. (US Pat. No. 6,571,005; Filed Apr. 21, 2000).

Art Unit: 1631

Applicant's arguments, filed 09/20/2006, that Li et al. (i) do not disclose indicating data concerning expression quantities for two samples with points plotted on a logarithmic coordinate system, (ii) do not disclose calculating a coefficient from a value of an intercept of an approximate straight line, and (iii) do not disclose performing division are not deemed to be persuasive for the reasons set forth below. Therefore this rejection is maintained for claims 3 and 4, and newly applied to claims 6, 7, and 8 as necessitated by amendment.

Regarding (i): Claims 3 and 4 do not require a "logarithmic" coordinate system, therefore this argument is not persuasive. Regarding (ii) and (iii): Claims 3 and 4 do not recite an "intercept of an approximate straight line," therefore this argument is not persuasive. However, Li et al. clearly teach determining the slope of a low intensity region and slope of a high intensity region (Fig. 2) and (Col. 3, lines 27-51). Li et al. also teach linear normalization using scaling factors that are "slopes" of lines [Col. 3, lines 10-20]. Li et al. also teach performing a division process where intensity of each EST on an array was divided by the mean intensities of all ESTs on that array and multiplied by a nominal average intensity value (Col. 3, lines 11-23). Therefore, for the reasons set forth above and in the previous office action, the Examiner maintains that Li et al. indeed teaches all of the limitations of claims 3 and 4.

Regarding newly added claims 6, 7, and 8: Claim 6 recites the exact same limitations as the claim from which it depends (claim 4). As claim 4 has been rejected for reasons set forth above, claim 6 is also rejected. As set forth in the previous office action, Li et al. teach plotting a graph gene expression data on a coordinate system from baseline and experimental array samples (Fig. 2), and determining PM-MM slope calculations with lines passing through an origin (Fig. 2), as in claims 7. This is also an implicit teaching for abnormal and normal cells as expression data is obtained from cells [Col. 2, lines 20-35]. Li et al. also teach performing a division process

where intensity of each EST on an array was divided by the mean intensities of all ESTs on that array and multiplied by a nominal average intensity value (Col. 3, lines 11-23), which is a teaching for performing a division by value of slope as in instant claim 7. Therefore, the Examiner maintains that Li et al. teaches all of the limitations of claims 3, 4, 6, 7, and 8.

Claim Rejections - 35 USC § 103

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (US Pat. No. 6,571,005; Filed Apr. 21, 2000), in view of Tseng et al. (Nucleic Acids Research, 2001, Vol. 29, No. 12, p. 2549-2557) and Quackenbush (Nature, 2002, p.496).

Applicant's arguments, filed 09/20/2006, that (i) Li et al. do not teach or suggest a straight line with slope 1 that is an approximate representation of the data or determining an intercept of a line with the vertical axis, and (ii) Tseng's methods are completely different are not deemed to be persuasive for the reasons set forth below. Therefore this rejection is maintained for claims 1-4 and newly applied to claim 5 as necessitated by amendment.

Regarding (i): It is noted that claims 1 and 2 do not specifically recite a step directed to "determining an intercept" as argued by applicant [Remarks, p.15, ¶ 4]. Therefore this argument is not persuasive. As no equations are recited in the claims that would serve to illustrate in what way "coefficients" are calculated from values of intercepts, the Examiner has broadly and reasonably interpreted this limitation to encompass the teaches of Li et al. Li et al. clearly teach linear normalization where intensity data is related as a straight line with a zero y-intercept [Col. 3, lines 10-20]. Li et al. teach determining approximately straight lines of various slopes through

Art Unit: 1631

an origin of a coordinate system, wherein said lines clearly intersect at various positions along the vertical axis (Fig. 2). Given these teachings of Li et al. and given that the limitation of a "slope of 1" is not a functional aspect of the instant method, these limitations have not been given patentable weight over the teachings of Li et al.

Regarding (ii): As set forth in the previous office action, Tseng et al. was relied upon as a teaching for plotting gene expression data using logarithmic graphs. Quackenbush was relied upon as motivation to combine methods Li et al. with the added step of logarithmic graphical representation of gene expression data as taught by Tseng et al. Quackenbush also teaches the logarithmic transformation of gene expression data in data normalization [p. 496, Col. 2], which provides a reasonable expectation of successfully combining Li et al. and Tseng et al. As the Examiner maintains that Li et al. teach the limitations of claims 3 and 4, as set forth in the previous office action and maintained above, he maintains that Li et al. combined with Tseng et al. and Quackenbush make obvious claims 1, 2, and 5 for reasons set forth in the previous office action and maintained above.

CONCLUSION

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 1631

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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